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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/989,758

Applicant(s)
GOLUB

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 15-20, and 37-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 15-20, and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: **Detailed Action**

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DETAILED ACTION

Status of the Application

1. The amendment received on June 18, 2003 has been entered. Claims 1, 4, 15, 19, and 37-40 are newly amended. Claims 1-5, 15-20, and 37-40 are pending and under consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 3-4, 8, 15, and 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Gocke et al. (U.S. Patent 6,156,504) (December 5, 2000).

Gocke et al teaches a method of classifying a lymphoma sample according to predicted treatment outcome comprising the steps of a) isolating a gene expression product from at least two or more informative genes from one or more cells in the sample; and b) determining a gene expression profile of two or more informative genes (Example 2, Column 25, line 35 to Column 26, line 13). Gocke et al teaches that the gene expression profile determined by this method correlates to treatment outcome, thereby classifying the sample with respect to treatment outcome, which is survival after treatment (Example 4). Gocke et al also teaches that the gene

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expression profile determined by this method correlates to lymphoma type, thereby classifying the sample with respect to lymphoma type (Examples 2 and 4)

Gocke et al teaches the embodiment in which the gene expression product is mRNA (Column 20, lines 51-65).

Gocke et al teaches the embodiment in which the gene expression profile is determined using hybridization probes specific to two or more of the informative genes (Column 19, lines 7-24 and Column 26, lines 31-40 and Column 28, lines 39-60).

Gocke et al teaches the embodiment in which the lymphoma is follicular lymphoma (Example 2).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Gocke et al. (U.S. Patent 6,156,504) (December 5, 2000) in view of Dalla-Favera and Raju (U.S. Patent 5,882,858) (May 28, 1996).

Gocke et al teaches the method of claims 1, 3-4, 8, 15, and 17-19 as described above.

Gocke et al does not teach the method, wherein the lymphoma is diffuse large cell lymphoma.

Dalla-Favera and Raju teaches the method, wherein the lymphoma is diffuse large cell lymphoma (Figures 12 and 13).

It would have been *prima facie* obvious to one having ordinary skill In the art at the time the invention was made to substitute and combine the method, wherein the lymphoma is diffuse large cell lymphoma of Dalla-Favera and Raju in the method of Gocke et al. since Dalla-Favera and Raju states, “This invention provides an assay for non-Hodgkin’s lymphoma, a method for screening putative therapeutic agents for treatment of non-Hodgkin’s lymphoma and a method for diagnosing B-cell lymphoma (Column 2, lines 41-44) ”. An ordinary practitioner would have been motivated to substitute and combine the method, wherein the lymphoma is diffuse large cell lymphoma of Dalla-Favera and Raju in the method of Gocke et al in order to achieve the express advantages, as noted by Dalla-Favera et al., of an invention which provides an assay for non-

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Hodgkin's lymphoma, a method for screening putative therapeutic agents for treatment of non-Hodgkin's lymphoma and a method for diagnosing B-cell lymphoma.

6. Claims 5, 20, and 37-40 are rejected under 35 U.S.C. 103(a) as being obvious over Gocke et al. (U.S. Patent 6,156,504) (December 5, 2000) in view of Perou et al. (Proc. Natl. Acad. Sci. USA, (1999), Vol. 96, pages 9212-9217).

Gocke et al teaches the method of claims 1, 3-4, 8, 15, and 17-19 as described above.

Gocke et al does not teach the method of determination of gene expression profile using oligonucleotide arrays. However, the use of microarrays to determine differences in gene expression between normal cells and tumor cells was well known to those of ordinary skill in the art at the time the application was filed. Perou, for example, teaches the use of DNA microarrays to demonstrate differences in the pattern of gene expression between normal human mammary epithelial cells and breast cancer (Figure 1).

Regarding claims 37 and 38, the claims recite the additional limitations to claim 1 that the gene expression product is isolated from at least five or ten informative genes. Perou teaches the embodiment in which the expression product is isolated from 22 genes (Figure 3A).

Regarding claims 39 and 40, the claims recite the additional limitations to claim 15 that the gene expression product is isolated from at least five or ten informative genes. Perou teaches the embodiment in which the expression product is isolated from 22 genes (Figure 3A).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the application was filed to modify the method of Gocke et al to include a microarray as taught by

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Perou because the demonstrated ability of the microarray to detect changes in a broad variety of genes in a single experiment (see for example figure 1). One of ordinary skill in the art would have been motivated to use a microarray because of the increased convenience compared to performing a large number of northern or Southern blots.

Response to Amendment

7. In response to amendment, all previous 112(first) and (second) paragraph rejections and 102(b) as well as 103(a) rejections have been withdrawn. However, new 102(a) and 103(a) rejections have been included.

Response to Arguments

8. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703)605-1237.

Arun Chakrabarti,

Patent Examiner,

August 26, 2003


GARY BENZION, PH.D.
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